ARGUMENTS / REMARKS

Claims 37-68 are pending in the application. Claims 1-36 are canceled. Claims 37-47, 58-61, 66 and 67 are currently amended.

I. Claim Objections

Claim 66 stands objected to because of the following informalities: Claim 66 recites "The computer readable media of claim 63, the instructions further comprising instructions for displaying the criteria selection interface to the user within a single screen such that the user does not have to school within the single screen while selecting criteria." Examiner suggests that there is a typographical error, and it should be "scroll", same as the second limitation of claim 37.

Applicant has amended Claim 66 according to the Examiner's suggestion and respectfully requests that the objection to Claim 66 be withdrawn.

II. Claim Rejections Under 35 U.S.C. 112, Second Paragraph

Claim 37 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner asserts, *inter alia*, it is not clear it the computer readable media recited in Claim 37, is only for launching to the server, or whether it was intended to include a navigation module, a verification module and a user interface.

The Applicant has amended Claim 37 and its dependant claims to more clearly state that the navigation module, the verification module and the user interface are stored on a computer readable medium operatively connected to a server, and that the navigation module, the verification module and the user interface are transmitted to a client device where they enable a method for collecting patient clinical encounter information.

III. Claim Rejections Under 35 U.S.C. 103(a)

Claims 37-68 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,047,259 to Campbell, et al. ("Campbell") in view of U.S. Patent No. 5,574,828 to Hayward, et al. ("Hayward".) Applicant respectfully traverses.

Independent Claim 37, as amended, is a method for collecting patient clinical encounter information. Computer-executable instructions comprising a navigation module, a verification module and a user interface are stored on a computer-readable medium operatively connected to a server. The user interface comprises a plurality of fields, at least one of the fields comprising a pop-up list, the arrangement of the plurality of fields being fixed and arranged as on a clinical chart. The navigation module, the verification module and the user interface are transmitted from the server to a client device. The client device is caused to display the user interface, including the plurality of fields, within a single screen to a user, the user interface facilitating the entry of patient clinical encounter information into the plurality of fields by not requiring the user to scroll the user interface within the single screen.

Patient clinical encounter information is received from the user via the user interface displayed on the client device. The navigation module on the client device is caused to modify the contents of the plurality of fields in response to the received patient clinical encounter information. At least one diagnosis is selected by the user via the user interface displayed on the client device. The verification module on the client device is caused to determine the authorization level for the at least one diagnosis by referring to the contents of the plurality of fields. The patient clinical encounter information and the at least one diagnosis are received by the server, via the network, from the client device after the determination of the authorization level for the diagnosis by the verification module.

Independent Claim 45, as amended, is a method for facilitating the submission of a clinical record for automated processing. Computer-executable instructions comprising a navigation module, a verification module and a selection interface are stored on a computer-readable medium operatively connected to a server. The selection interface comprises a plurality of fields within a single, the selection interface facilitating selection by the user of a plurality of predetermined clinical data types, the predetermined clinical data types comprising data necessary for creating at least a record of the symptoms associated with a patient and a diagnosis. The navigation module and the selection interface are transmitted, via a network, from the server to a client device. The client device is caused to display the selection interface to a user. A selection is received from the receiving a selection from the selection interface. The navigation module on the client device is caused to add at least one data field in response to the selection,

the data field being selected by a navigation module, to the displayed selection interface, the data field being quantified and associated with an objective criteria, the data field facilitating automated processing of the clinical record.

Independent Claim 47, as amended, is a computer readable media having instructions for facilitating the submission of a clinical record for automated processing. A diagnosis is received from a user via a user interface running on a client device. A criteria selection is received from the user via the user interface, the criteria being selected from a pre-defined list of criteria associated with the diagnosis, the criteria associated with a rule required for confirming the diagnosis, the criteria associated with at least one finding. Data is received from the user via the user interface corresponding to at least a subset of the findings associated with the user selected criteria. The client device is caused to verify, without interaction with a server, that all necessary data associated with the diagnosis has been received from the user. The client device is caused to transmit from the user to the server to facilitate creation by the server of an electronic clinic record based on the data.

Independent Claim 49 is a computer having instructions for providing a user interface for entering data for evaluating a clinical encounter. The user interface comprises an interactive set of lists, each of the lists in the interactive set of lists having its own domain, and each of the lists in the interactive set of lists being displayed as a separate pop-up button list within a single screen, at least a subset of the lists being hierarchically related, the interactive set of lists being formatted to be similar to a clinical chart.

Independent Claim 58, as amended, is a method for collecting patient clinical encounter information. At least one form, a first set of rules and a second set of rules are stored on a computer-readable medium operatively connected to a server. The forms, the first set of rules, and the second set of rules are transmitted by the server to a client device. The client device is caused to display the forms. A first subset of the forms are configured to apply the first set of rules to a first subset of inputs entered into the first subset of forms. A second subset of forms is configured to apply the second set of rules to at least a second set of inputs entered into the second subset of forms. Patient clinical encounter data is received from at least one user via the forms displayed on the client device. The client device is caused to process the received patient clinical encounter data on the client device in accordance with the first and second set of rules

Independent Claim 62 is computer readable media having instructions for providing a facilitating the single screen submission of patient clinical encounter information. A clinical element selection interface is provided, the clinical element selection interface facilitating the selection of a clinical element, the clinical elements comprising at least one of history and exam. A system/group selection interface is provided, the system/group interface facilitating the selection of a system/group associated with the selected clinical element, the system/group interface being populated based upon the selected clinical element. A parameter selection interface is provided, the parameter selection interface facilitating the selection of a parameter associated with the selected system/group, the parameter selection interface being populated based upon the selected system/group. A client device is caused to display the clinical element selection interface, the system/group interface and the parameter selection interface within a single screen.

Independent Claim 63 is a computer readable media having instructions for determining the appropriateness of patient clinical encounter information. A client device is caused to display a criteria selection interface to a user, the criteria selection interface allowing the user to select a diagnosis-based criteria. Diagnosis related data is received from the user. The client device is caused to apply a verification rule to the received diagnosis related data, the verification rule providing a verification result, the verification result providing an authorization level for each selected criterion in the criteria selection interface.

Campbell is directed to a software system for managing a health care practice includes interactive software tools for conducting a physical exam, suggesting tentative diagnosis, and managing a treatment protocol. The physical exam software guides the user through a physical exam, prompting the user for input and dynamically generating context sensitive questions based on prior input. The diagnosis software generates a list of possible diagnoses based on the observations recorded from the physical exam. The user can interactively select a diagnosis by selecting a diagnosis from a rule out list and watching the display as the system dynamic updates the status of unresolved symptoms. The user can also select a treatment protocol, which is integrated with future physical exams. The treatment protocol is integrated such that future exam sessions reflect the status of the treatment protocol and remind the user which services need to be performed and when they should be performed.

Hayward is directed to a system utilizing a software program used to write other software application programs for the implementation of guideline applications for use in situations where a qualification decision or next course of action determination must be made. The system uses questions with limited choice answers. Data provided in answer to the questions causes a second program application to be automatically generated based on the answers. The second application then elicits responses in an interactive manner. Qualification decisions and courses of action are suggested as an output of the second application. Means are provided for evaluating the reliability of the suggestions based on consistency of answers and fatigue of the user. Means are also provided for editing either application program. In one embodiment, the system uses a pop-up for displaying a keyword list

With respect to independent Claim 37, as amended, Campbell does not disclose transmitting, via a network, a navigation module, a verification module and a user interface having at least one pop-up list from the server to a client device. At most, Campbell discusses, in general terms, (a.) software implemented in a series of program modules executed either on a server or client computer that (b.) may be ported to other computer system configurations, and that (c.) program modules may be located in both local memory of a client computer and remote memory such as in the server computer. Campbell, col. 4, ln. 1-18. There is no discussion of any active transmission of program modules between server and client machines during the process of collecting patient encounter information. The interface in Campbell makes no use of pop-up lists.

Campbell does not disclose a verification module on the client device that determines an authorization level for at least one diagnosis. Rather, Campbell discloses a system where (a.) different functions may be assigned to different computers (Campbell, col. 5, lines 33-61) (b.) the authority to make diagnoses (and other perform other functions) can be limited to specific users (Campbell, col. 6, 21-46), and (c.) given a set of symptoms, the system suggests a set of possible diagnoses (Campbell col. 16, ln. 65 - col. 17, ln. 10.) In the present Application, the authorization level for a diagnosis is used to determine what level of treatment is authorized for any specific clinical event. For example, the standard authorization level for a patient in the hospital is “acute level of care,” however the authorization for a patient in an intensive care unit

would be "intensive level of care." See, e.g. para. [0059] of the present application. Campbell discloses no such function.

Hayward does nothing to remedy the deficiencies of Campbell cited above. Specifically, Hayward does not disclose or suggest transmitting, via a network, a navigation module, a verification module and a user interface having at least one pop-up list from the server to a client device. In fact, Hayward makes no mention, whatsoever, of clients, server or networks and simply describes a software program used to write other software application programs. Furthermore Hayward does not disclose a verification module on a client device that determines an authorization level for at least one diagnosis. The system in Hayward relates to automatic generation of computer programs and provides no functionality, whatsoever, that relates to entry of medical information.

The Examiner apparently cites Hayward, in part, for the general proposition that pop-up lists were known in the art at least as early as 1996. The same could be said for any other user interface element used in the present invention. It is the use of pop-up lists in the manner specifically described in the Application that is claimed, not the mere use of pop-up lists in the abstract. The Examiner has failed to particularly point out how Hayward renders the Applicant's use of pop-up lists *as claimed* obvious. The meaning of the Examiner's further statement that "[i]t would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Hayward with the motivation of generating [sic] second program automatically based on the answers to the questions" is not clear, since neither the present invention nor Campbell generate programs.

Furthermore, the Examiner has not advanced a sufficient rationale as to why a person skilled in the art would have been motivated to combine Campbell and Hayward in the manner described in the present Office Action. A factfinder should be aware of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning. KSR Int'l Co. v. Teleflex, 127 S.Ct at 1742. In determining whether a claimed invention is an obvious combination of prior art references, it must be shown there is an apparent reason to combine the known elements in the fashion claimed. Id. at 1741. *To facilitate review, this analysis should be made explicit*. Id. No such analysis was provided.

Independent Claim 45 and its dependants have been amended to more clearly state that the referenced navigation module and selection interface are stored on a computer readable medium operatively connected to a server, and that the navigation module, the verification module and the user interface are transmitted to a client device where they enable a method for facilitating the submission of a clinical record for automated processing.

With respect to independent Claim 45, as amended, Campbell does not disclose transmitting, via a network, a navigation module and a selection interface from the server to a client device. At most, Campbell discusses, in general terms, (a.) software implemented in a series of program modules executed either on a server or client computer that (b.) may be ported to other computer system configurations, and that (c.) program modules may be located in both local memory of a client computer and remote memory such as in the server computer. Campbell, col. 4, ln. 1-18. There is no discussion of any active transmission of program modules between server and client machines during the process of collecting patient encounter information.

Hayward does nothing to remedy the deficiencies of Campbell cited above with respect to independent Claim 45. Specifically, Hayward does not disclose or suggest transmitting, via a network, a navigation module and a selection interface having at least one pop-up list from the server to a client device. In fact, Hayward makes no mention, whatsoever, of clients, server or networks and simply describes a software program used to write other software application programs.

Independent Claim 47 has been amended to more clearly state that user data is received via a user interface on a client device and that the client device verifies the data without interaction with a server.

With respect to independent Claim 47, as amended, Campbell does not disclose a system having a criteria associated with rules required for confirming diagnoses that have been entered by a user. Rather, Campbell discloses a system wherein given a set of symptoms, the system suggests a set of possible diagnoses (Campbell col. 16, ln. 65 - col. 17, ln. 10.) Furthermore, Campbell does not disclose a system wherein a client device is caused to verify, without interaction with a server, that all necessary data associated with the diagnosis has been received

from the user. Rather, Campbell discloses a system wherein client machines are in constant communication with a server. See, e.g. Campbell, col 14, ln 19-21 ("The data displayed in this and other exam screens is dynamic in that it is updated by the server soon after it is entered.")

Hayward does nothing to remedy the deficiencies of Campbell cited above with respect to independent Claim 47. Specifically, Hayward does not disclose or suggest a system having a criteria associated with rules required for confirming diagnoses that have been entered by a user. The system in Hayward relates to automatic generation of computer programs and provides no functionality, whatsoever, that relates to entry of medical information.

With respect to independent Claim 49, Campbell does not disclose sets of lists being displayed as a separate pop-up buttons lists within a single screen, the interactive set of lists being formatted to be similar to a clinical chart. Campbell, does not in fact, disclose the use of pop-up buttons at all. Furthermore, Campbell does not disclose an interface using lists hierarchically related to one another. With respect to the examples cited by the Examiner, Campbell, FIG. 10 and col. 17, ln. 46-52, discloses a diagnostic protocol screen with the patient banner, a tentative diagnosis box, recommended therapy box, a diagnosis status check list and navigational control buttons.

Only the recommended therapy "box" resembles a list, and is not hierarchically related to another list. Campbell, col. 12, line 59 to col. 13, line 20 describes physical exam buttons represent the top level in a hierarchy of physical exam *screens* wherein when the user clicks on any of these buttons, the system launches a new screen. There is no mention of hierarchically related *lists*. Campbell, col. 1, line 62 to col. 2, line 13, discusses, in general terms, a system that interactive user interface screens for conducting an interactive medical exam, generating diagnoses of abnormal observations, and managing a treatment protocol. There is no mention of hierarchically related *lists*.

Hayward does nothing to remedy the deficiencies of Campbell cited above. Specifically, Hayward does not disclose or suggest disclose sets of lists being displayed as a separate pop-up buttons lists within a single screen, the interactive set of lists being formatted to be similar to a clinical chart. The system in Hayward relates to automatic generation of computer programs and provides no functionality, whatsoever, that relates to entry of medical information.

Independent Claim 58 and its dependants have been amended to more clearly state that the referenced form, first set of rules and second set of rules are stored on a computer readable medium operatively connected to a server, and that the form, first set of rules and second set of rules are transmitted to a client device where they enable a method for collecting patient clinical encounter information.

With respect to independent Claim 58, as amended, Campbell does not disclose transmitting, via a network, at least one form, a first set of rules and second set of rules from the server to a client device. At most, Campbell discusses, in general terms, (a.) software implemented in a series of program modules executed either on a server or client computer that (b.) may be ported to other computer system configurations, and that (c.) program modules may be located in both local memory of a client computer and remote memory such as in the server computer. Campbell, col. 4, ln. 1-18. There is no discussion of any active transmission of program forms or rules between server and client machines during the process of collecting patient encounter information.

Hayward does nothing to remedy the deficiencies of Campbell cited above with respect to independent Claim 58. Specifically, Hayward does not disclose or suggest transmitting, via a network, at least one form, a first set of rules and second set of rules from a server to a client device. In fact, Hayward makes no mention, whatsoever, of clients, server or networks and simply describes a software program used to write other software application programs.

With respect to independent Claim 62, Campbell does not disclose a system wherein client device is caused to display a clinical element selection interface, a system/group interface and a parameter selection interface within a single screen. With respect to the examples cited by the Examiner, Campbell, col. 13, line 66 to col. 14, line 8, and FIG. 5, discloses "graphical user interface controls prompt the user to enter information because they display an item to be observed and then give the user an option to make some observation for that item." In FIG. 5, the user can select the overall condition or temperature observation by checking a check button, enter numerical data such as temperature via a graphical box or enter or select text input from

drop-down boxes. The screen does not provide a clinical element selection interface, a system/group interface and a parameter selection interface.

Hayward does nothing to remedy the deficiencies of Campbell cited above with respect to independent Claim 62. Specifically, Hayward does not disclose or suggest disclose a system wherein client device is caused to display a clinical element selection interface, a system/group interface and a parameter selection interface within a single screen. The system in Hayward relates to automatic generation of computer programs and provides no functionality, whatsoever, that relates to entry of medical information.

With respect to independent Claim 63, Campbell does not disclose a criteria selection interface wherein a verification rule is applied to a received diagnosis in order to determine an authorization level for each selected criterion in the criteria selection interface. Rather, Campbell discloses a system where (a.) different functions may be assigned to different computers (Campbell, col. 5, lines 33-61) (b.) the authority to make diagnoses (and other perform other functions) can be limited to specific users (Campbell, col. 6, 21-46), and (c.) given a set of symptoms, the system suggests a set of possible diagnoses (Campbell col. 16, ln. 65 - col. 17, ln. 10.) As noted above, In the present Application, the authorization level for a diagnosis is used to determine what level of treatment is authorized for any specific clinical event.

Hayward does nothing to remedy the deficiencies of Campbell cited above with respect to independent Claim 63. Specifically, Hayward does not disclose or suggest a criteria selection interface wherein a verification rule is applied to a received diagnosis in order to determine an authorization level for each selected criterion in the criteria selection interface. The system in Hayward relates to automatic generation of computer programs and provides no functionality, whatsoever, that relates to entry of medical information.

With respect to independent Claim 67, the present Office Action appears to indicate that that independent Claim 67 and its dependant 68 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell in view of Hayward. The Examiner, however, fails to elaborate on such a rejection, and, later in the Office Action rejects Claims 67-68 using an additional reference, stating “Campbell fails to expressly teach transformation of physical patient charts for

review by health care review organizations." Applicant presumes inclusion of Claims 67-68 in the group of claims rejected as unpatentable over Campbell in view of Hayward is a typographical error, and will respond to the separate rejection of Claims 67-68 below.

Claim 46 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell in view of Hayward and further in view of U.S. Patent Publication No. 2001/0037218 Al to Kaker et al. ("Kaker".) Applicant respectfully traverses.

Claim 46 depends on independent Claim 45 and is further directed to a system wherein the selection interface and at least one data field being provided via an HTML web page on the Internet.

Kaker discloses an online system for providing prescription assistance for indigent patients using programs provided by pharmaceutical manufacturers comprises a web server connected to the internet; a database connected to the web server, the database including names of manufacturers of drugs providing prescription assistance to indigent patients and their respective application forms required to be filled out to participate in the programs; at least one workstation connected to the web server through the internet; and software operably associated with the web server and the database for searching the database for application forms by a user located at the workstation by selecting manufacturer name or drug name, for viewing the forms on a monitor, for filling out the forms for a patient and printing the forms for sending to the manufacturer.

Kaker does not remedy the deficiencies of Campbell and Hayward discussed above with respect to Claim 45 Specifically Neither Campbell nor Hayward nor Kaker disclose or suggest transmitting, via a network, a navigation module and a selection interface from a server to a client wherein the selection interface facilitates selection by the user of a plurality of predetermined clinical data types, the predetermined clinical data types comprising data necessary for creating at least a record of the symptoms associated with a patient and a diagnosis

Claims 67 and 68 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell and Hayward in view of U.S. Patent No. 5,301,105 to Cummings, Jr. ("Cummings".) Applicant respectfully traverses.

Independent Claim 67 has been amended to more clearly state that the client device verifies diagnoses without interaction with a server and that that the criteria used to verify diagnoses on the client device are set by health care reviewing organization that receive transmission of electronic clinical records relating to the diagnoses.

Independent Claim 67, as amended, is computer readable media having instructions for an electronic clinical record creation and review system. A client device is caused to display a user interface, the user interface prompting the user for clinically relevant inputs. Clinically relevant inputs are received from the user, the clinically relevant inputs comprising a diagnosis and at least one patient symptom, the symptom being clinically relevant to the diagnosis. The client device is caused to verify, without interaction with a server, the diagnosis by ensuring that sufficient symptoms have been received to satisfy at least one authorization criteria, wherein the at least one authorization criteria has been set by a health care reviewing organization. The client device to is caused to generate an electronic clinical record on the client device and to transmit the electronic clinical record to the health care reviewing organization for review.

Cummings describes a fully integrated and comprehensive health care system that includes the integrated interconnection and interaction of the patient, health care provider, bank or other financial institution, insurance company, utilization reviewer and employer so as to include within a single system each of the essential participants to provide patients with complete and comprehensive pre-treatment, treatment and post-treatment health care and predetermined financial support therefor.

Neither Campbell nor Hayward nor Cummings disclose or suggest a system wherein a client device is caused to verify, without interaction with a server, a diagnosis by ensuring that sufficient symptoms have been received to satisfy at least one authorization criteria, wherein the at least one authorization criteria has been set by a health care reviewing organization. The Examiner acknowledges that Campbell fails to expressly teach transformation of physical patient charts for review by health care review organizations. The system in Hayward relates to automatic generation of computer programs and provides no functionality, whatsoever, that relates to entry of medical information. Cummings merely stands for the proposition that an integrated medical system may be in communication with an insurance company, but does not

discuss client systems which use, without interaction with a server, authorization criteria supplied by a health care reviewing organization to verify diagnoses.

It is well established that, in order to show obviousness, all limitations must be taught by the prior art. In Re Royka, 180 U.S.P.Q. 580, 490 F.2d 981 (CCPA 1974); MPEP § 2143.03. It is error to ignore specific limitations distinguishing over the references. In Re Boe, 184 U.S.P.Q. 38, 505 F.2d 1297 (CCPA 1974); In Re Saether, 181 U.S.P.Q. 36, 492 F.2d 849 (CCPA 1974); In Re Glass, 176 U.S.P.Q. 489, 472 F.2d 1388 (CCPA 1973).

Since, as argued above, independent Claims 37, 45, 47, 49, 58, 62, 63 and 67 contain elements neither expressly or inherently described by any of the cited references, independent Claims 37, 45, 47, 49, 58, 62, 63 and 67 and their dependant claims are patentable over any combination of the cited references. Therefore, Applicant respectfully requests that the rejections of Claims 37-68 under 35 U.S.C. 103(a) be withdrawn.

IV. Conclusion

Having responded to all objections and rejections set forth in the outstanding Office Action, it is submitted that claims 37-68 are in condition for allowance and Notice to that effect is respectfully solicited. In the event that the Examiner is of the opinion that a brief telephone or personal interview will facilitate allowance of one or more of the above claims, the Examiner is courteously requested to contact applicant's undersigned representative.

The Commissioner is authorized to charge any additional fees associated with this filing, or credit any overpayment, to Deposit Account No. 50-2638. If an extension of time is required, this should be considered a petition therefor.

Respectfully submitted,

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